

Serial No. 10/721,582

PATENT

DRAWING AMENDMENTS

A new complete set of corrected formal drawings that include Figures 26, 26A, and 50 are enclosed.

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REMARKS

In the Office action of March 31, 2005, Paper No. 40, claims 1, 4-10, 12 and 13 were pending with claims 2, 3 and 11 having been withdrawn from consideration. All claims are rejected. In particular, claim 13 is rejected under 35 U.S.C. 112, second paragraph as being indefinite. Claims 1, 4-10, 12 and 13 are rejected under U.S.C. 102(e) as being anticipated by DiMatteo et. al. By this amendment, claims 4-6, 8-10, and 12-13 are cancelled without prejudice. New claims 14-25 are being introduced such that claims 1, 7, and 14-25 are pending at this time.

Claim Objections

The cancellation of claim 13 renders the objection moot.

Claim Rejections 35 USC § 112

The cancellation of claim 13 renders this rejection moot.

Claim Rejections 35 USC § 102

Applicants have amended claim 1 to positively recite the structure of the folded edge wherein 'the wall-engaging outer edge of each of the one or more leaflets comprises a folded edge of the biomaterial'. DiMatteo et al. (USPN 6,440,164) discloses a generally tubular support frame (scaffold 30) that further includes a series of leaflets comprising a covered frame in which the leaflets extend inward from the scaffold to contact one another to restrict flow and function as a vascular valve. The exemplary covered typically consists of an inner liner and an outer liner which are laminated to one another to 'sandwich' the support structure therebetween. The leaflets, which are clearly not configured to engage the walls of the vessel in the cited reference, therefore do not have a

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folded edge of biomaterial that forms the outer edge of the leaflet and which engages the walls of the vessel. It is an important distinction in that the biomaterial leaflet covering of Applicant's invention folds over the strut that resiliently engages the wall, thus providing an interface of biomaterial therealong for tissue ingrowth and providing a superior seal between the valve (leaflet) and the vessel wall. By folding the biomaterial over the support frame and attaching it to itself behind the strut, the integrity of the biomaterial is maintained and its bioactive constituents (e.g., the collagen matrix/scaffold, growth factors, etc.) are preserved. The DiMatteo reference teaches laminating the liner(s) and does not disclose preserving a folded edge along the outer edge of leaflet to engage the vessel walls. Indeed, the preferred embodiments of DiMatteo et al. are clearly polymeric liners where such the advantage of preserving an wall-engaging edge suitable for direct tissue ingrowth thereinto is not relevant. While biological materials are listed as alternative embodiments, there lacks any discussion of using them as a seal or interface between the support frame of the leaflets and the walls of the vessel.

Claims 7 has also been amended to require that the folded edge of biomaterial comprises the wall-engaging outer edge of the leaflet. This structure is clearly not taught in the DiMatteo reference where the outer edges of the leaflets do not even engage the walls of the vessel, but rather extend inward away from the walls.

Because the DiMatteo patent cited by the Examiner clearly lacks the teaching of the leaflet structure required in amended Claims 1 and 7, that reference cannot be found to anticipate and therefore, the rejection should be withdrawn. Applicants respectfully ask that these claims and all claims depending therefrom be passed to issue.

#### New Claims

New Claims 14-25 have been added by this amendment. Each positively recites the structure of the wall-engaging outer edge of the leaflets

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including the folded edge over the support structure. Therefore, Applicants' respectfully ask that these claims be allowed.


Summary

By this action, claim 1,7, and 14-25 are now pending in the application, claims 14-25 having been added as new. Claims The reexamination and reconsideration of the claims of this application is respectfully requested, and it is further requested that the application be passed to issue. If any issues remain after the Examiner has considered this amendment, it is being requested that the Examiner please telephone Applicants' representative, Mr. Agnew, to discuss setting up a personal interview.

Respectfully submitted,

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